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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/488,307	03/05/90	GREGORY	R IG490

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RECEIVED
MAR 27 1992
MARK A. HOFER

EXAMINER	
NISBET, T	

ART UNIT	PAPER NUMBER
1806	7

DATE MAILED: 03/24/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

Docketed/DAC
6/24/92 Response due

☒ This application has been examined ☒ Responsive to communication filed on 12/23/91 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-88 are pending in the application.
   Of the above, claims 1-45, 64-82, 85, & 87 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 46-63, 83-84, 86, & 88 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 46-63, 83-84, 86 and 88, drawn to protiens and therapeutic compositions, classified in Class 530, subclass 350.

II. Claims 1-45 and 76-77, drawn to DNA, vectors and host, classified in Class 435, subclass 69.1.

III. Claims 64-70, drawn to methods of treatment, classified in Class 424, subclass 516.

IV. Claims 71-75 and 78-82, drawn to methods of screening and kits, classified in Class 206, subclass 569.

V. Claims 85 and 88, drawn to transgenic animals, classified in Class 800, subclass 2.

16. The inventions are distinct, each from the other because of the following reasons:

17. The proteins and compositions of Group I represent expression products of the DNA, vectors, and cells of Group II. As such these proteins and pharmaceutical compositions represent separate and distinct inventions because they are separate and distinct classes of molecules, hence the separate classification. Furthermore, the examination of pharmaceutical compositions of Group I would include the search of classes not coextensive with the examination of the claims of Group II. Furthermore, the examination of the distinct groups requires the consideration of different aspects for each group which are not necessary for the examination of the other group. For example, the examination of proteins requires consideration of contaminants while the examination of Group II requires consideration of various genetic control sequences for the functional expression of the gene. In addition, the proteins of Group I can be synthesized by different means (chemical). In addition, the DNA sequences of Group II are also capable of separate use as probes for screening of DNA libraries or isolation of nucleic acid fragments. Therefore, for these reasons the two groups are considered to represent separate and distinct groups with searches that are not coextensive and which represent a serious burden to the examiner.

18. Inventions Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the proteins and pharmaceuticals are capable of being used to generate antibodies.

19. Inventions Group II and Groups III and IV and are related as product and process of use. The inventions can be shown to be

distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the DNA of group I can be used separately to study the gene expression of a variety of different promoters.

20. The methods of Group III and IV are methods of use of distinct products as set forth in paragraph 17 supra. Therefore, since the products are distinct, the methods of use are also distinct. In addition the methods of Group III and IV represent separate utilities. The method of Group III is a method of treatment for a patient while the method of Group IV does not involve the utility of therapy as method of screening are confined to in vitro situations.

21. The transgenic animals of Group V are separate from the products of Groups I and II as the proteins of Group I are separate from the genes or DNA molecules of Group II and as such are distinct from the transgenic animals of Group V. In addition the proteins have separate use as pharmaceuticals or as antigens for the generation of antibodies. The products of Group II, the DNA or genes, are also capable of separate use for the purpose of studying gene regulation with a variety of different promoters or as a probe for the isolation of homologous sequences. Since the transgenic animals of Group V are separate from the products of Groups I and II, the products of Group V must be separate from the methods of use of Groups I and II.

22. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recohnized divergen subject matter, restriction for examination purposes as indicated is proper.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

24. Applicants have elected to prosecute Group I of the previous restriction requirement of Paper No. 2. Since the current Group I contains all the claims of the previous Group I as well as some

extra claims. The present Group I will be considered to be constructively elected by original presentation for the following examination on the merits.

25. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

27. Claims 46-63, 83-84, 86 and 88 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Wilson.

The claims recite generically a variety of cystic fibrosis membrane conductance regulators which are essentially claimed in product by process form. As it is a well established principle that the process by which a product is made does not alter the product per se.

The Wilson reference provides a methods for the purification and isolation of the Cystic Fibrosis Protein (CFP) are also disclosed, see for example the last sentence of the abstract. See also the bottom of column 4 bridging to column 5 where specific protocols for the isolation and purification of CFP are disclosed. In so far as the claims are not limited in any way to the type of transmembrane regulator, the reference anticipates the claims as filed. Applicants are invited to provide a showing that the instant protein of Wilson is not the same as that of applicants invention.

In the alternative that applicants should show that the instant protein of the Wilson application is not the same as applicants, the production of such broad claims as that of the instant invention would be rendered obvious given the explicit teaching of Wilson for the production of monoclonal antibodies for the isolation of any cystic fibrosis proteins. See for example lines 25-46 of column 6.

28. Claims 46-63, 83-84, 86 and 88 are rejected under 35 U.S.C. § 103 as being unpatentable over Riordan et al.

The scope of the instant claims has been discussed supra.

The Riordan reference teaches the consensus cDNA sequence for the CFTR protein of the instant invention. The predicted amino acid sequence and the secondary structure of the expression product are also predicted in the Riordan disclosure giving one of ordinary skill in the art sufficient knowledge for the synthesis of the full length cDNA. Riordan lacks the actual expression of the cDNA, nor has the cDNA actually been isolated. However, these distinctions are not considered patentable because the once the DNA sequence of the gene is known DNA synthesizers exist within ordinary skill in the art for the ~~the~~ synthesis of a gene, given the sequence. Also, primers might be synthsized which would be useful for the screening of cDNA libraries for the isolation of either the genomic or cDNA sequence. Such techniques are within the purview of the skilled artisan. Should applicant question the capability of such techniques, references will be supplied to support the assertion. The lack of expression of the cDNA of Riordan is not considered of patentable import because applicants constructs have not been expressed either. Since the instant specification fails to provide examples showing expression of the cDNA of Riordan, the expression of the known and disclosed cDNA

sequence of Riordan for the production of a functional protein is considered within the ordinary skill of the art.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TMN
March 23, 1992

JOHN J. DOLL
SUPERVISORY PATENT EXAMINER
GROUP 180

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 3-78) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER	
NOTICE OF REFERENCES CITED	07/488,307	1806		5
	APPLICANT(S) Gregory et al			

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	4332274	5/30/82	Wilson et al			
	B						
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

*		
*	R	Riordan et al Science, 245: 1066-1073 (1989) Identification of the Cystic Fibrosis Gene: ....
	S	
	T	
	U	

EXAMINER	DATE
NISBET	3/16/92

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)